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Diabetic Foot Ulcer Ecosystem

Case-study for STS Roundtable Sep 2017

Background to case-study

- ITI Scotland had £7.9m ($10.5m) to fund the development of a technology platform that enables healthcare professionals to detect and diagnose infections in diabetes-related and other chronic wounds at the point of care.

- We completed a comprehensive review of point-of-care wound care practitioner requirements for an infection detection and diagnosis solution as well as the factors influencing its adoption in clinical and community environments.

- In addition, we examined:
  - the technology landscape for POC infection diagnostics
  - the competitive landscape
  - the status of research into host biomarker detection
  - The detailed health economic case in four markets (UK, US, DE, IN) for different DFU POC infection diagnostic technology platforms
  - Expert clinician / key opinion leader perspectives

Diabetic Foot Ulcer (DFU) infection ecosystem study

Study questions

ECOSYSTEM GROWTH OPPORTUNITY AND VALUE

What is the specific nature of the market opportunity for rapid point-of-care DFU infection diagnostics (by health market, size, growth projection, value, commercial and investment case)?

ECOSYSTEM DIVERSITY

How do we understand the diversity of ecosystem actors, especially their different values, resources, goals and contexts?

ECOSYSTEM RELATIONSHIPS AND INTERDEPENDENCIES

What hidden ecosystem segments exist that cut across common assumptions, definitions and levels?

VALUE FRAMES AND PROPOSITIONS

What diagnostic and related propositions (Value Frames) are most likely to be adopted and reimbursed by different health systems and ecosystem segments? How do we avoid overdesigning interventions and technologies?

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Study questions

ECOSYSTEM ADAPTATION AND DYNAMICS

What is the competitive threat and how is it likely to evolve and manifest? What is the status and likely development of biomarker technology? How will developments in adjacent ecosystems influence opportunity and adoption?

EMERGENT STRATEGY DESIGN

What is the optimum ecosystem strategy for intervention, and with what diagnostic concepts? How to evolve the market?

What are the risks and constraints to adoption in current practice? What is the technology strategy and roadmap?

CONCEPTS AND DEVELOPMENT SPECIFICATIONS

What are the segment user and functional requirements specifications of these concepts, to feed into development?

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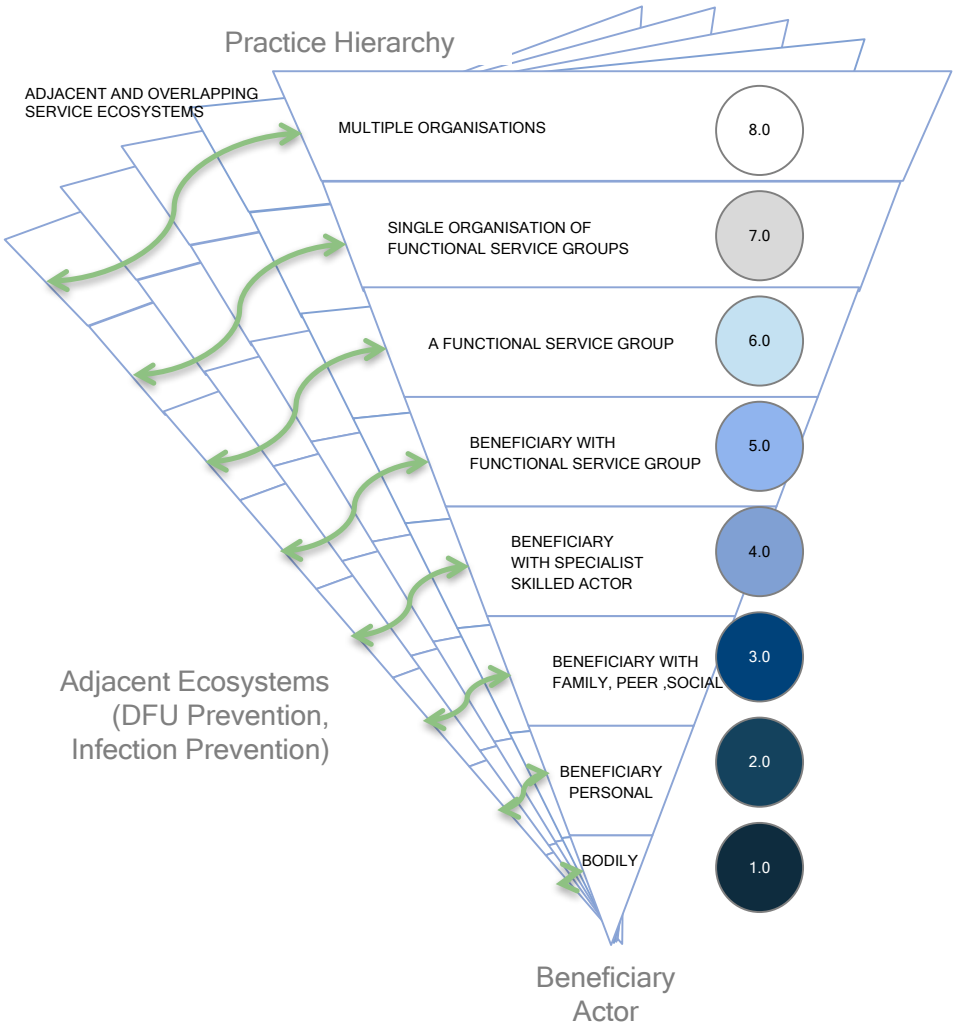
Primary Levels and Actors in focus



Level 8 – MULTIPLE ORGANISATION INTERACTIONS

Interactions between single healthcare organisations and regulators, reimbursement bodies, other payers and influencers

Level 7 – SINGLE ORGANISATION OF FUNCTIONAL SERVICE GROUPS

Interactions between diabetic foot clinics, outpatients, labs, community practices, wards and payers

Level 6 – FUNCTIONAL SERVICE GROUP

Diabetic foot clinic, podiatry clinic, outpatients, microbiology labs, surgery

Level 5 – BENEFICIARY WITH FUNCTIONAL GROUP

Patient interactions with specialist diabetic foot clinic, with GP practice, with podiatry clinic, with outpatients and with pharmacies; nurse interactions with GP practice, and with microbiology lab technicians

Level 4 – BENEFICIARY WITH SPECIALIST SKILLED ACTOR

Podiatrist, community and GP nurse, tissue viability nurse, doctor, diabetic nurse and diabetologist interactions with patients

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Study facts

- Completed in 12 week period
- Team of 3 Umio consultants
- Four distinct health markets: UK, US, Germany and India
- 65 x practitioner 40 minute 1:1 interviews on location
- 4 x on-site functional service group observations including discussions with patients
- 400 x 30 minute surveys followed by 100 x 5 minute follow-up surveys to capture performance data
- 6 x resource and cost data capture follow-up interviews
- 2 x co-creation workshops with KOLs and practitioners
- 4 x wound care KOL post-study validation interviews

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Study outputs

- One detailed service ecosystem map of patient, practitioner, microbiologist, payer interactions
- 175 practitioner and microbiologist contexts, unmet needs, desired outcomes and related capability gaps
- One problem situation specification (ecosystem trends and contexts)
- One biomarker development status review
- One holistic health ecosystem practitioner segmentation consisting of four hidden segments grouped by common values, risks, resources, unmet needs
- Eight distinct value propositions and technical concepts
- Four separate health economic models (MARKOV, QALY) for each health market and for 4 different ecosystem intervention scenarios
- A competitive analysis report exploring adjacent ecosystems
- One overall market access and growth strategy
- Four separate health market commercial cases including addressable market size, bill of materials, pricing and margin analysis
- One 60 page summary document of recommendations

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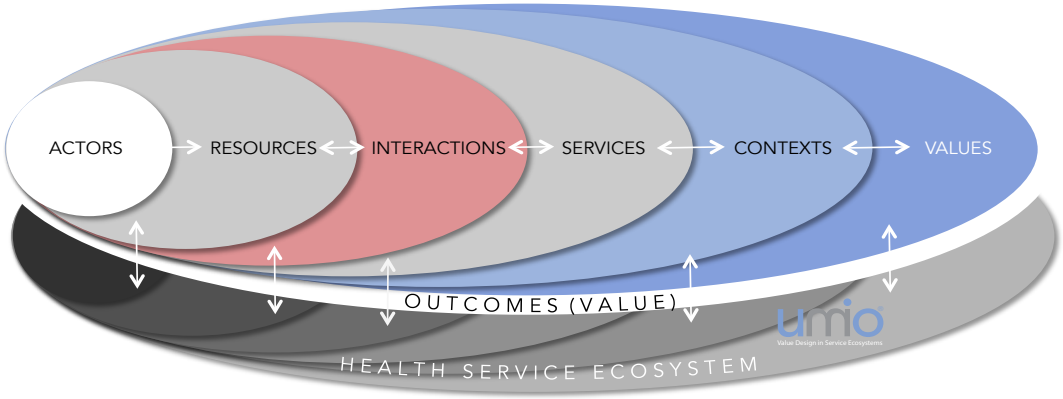
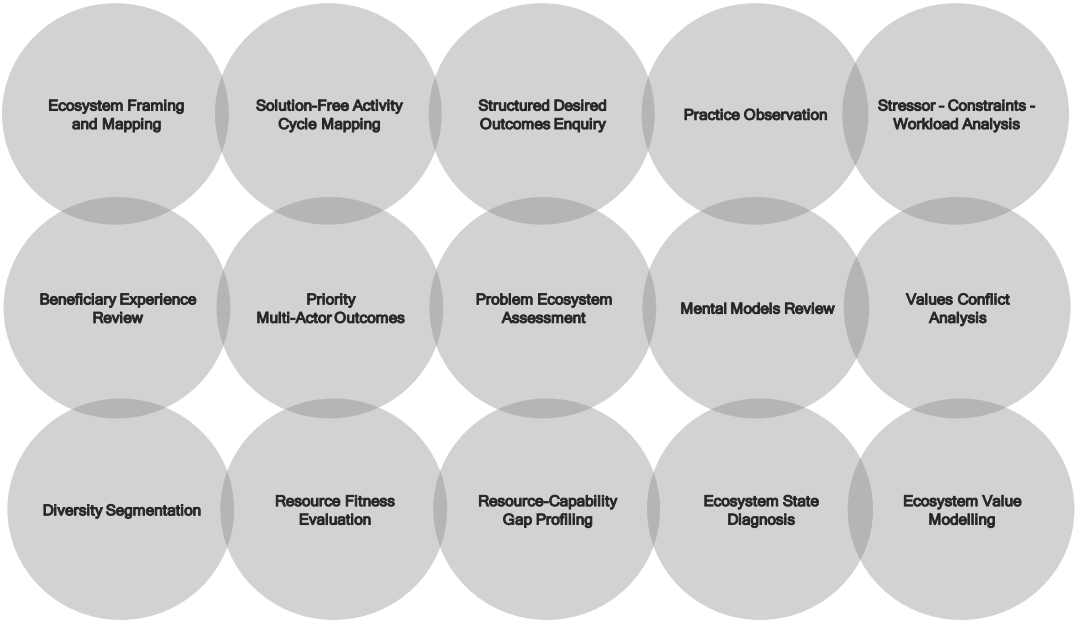
Studying Practices in a Health Service Ecosystem

We deploy a variety of methods to study one or more of the practices at the different levels of a framed ecosystem.

The following sentence defines the "units of analysis" we study to enquire into practices and reveal problems, conflicts, opportunities, themes, patterns, relationships and priorities for improvement.

Influenced by values, human actors interact with tangible and intangible resources and each other to perform or obtain services in an effort to co-create outcomes (value) for a particular health ecosystem context





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“Value in use” and technology evolution example

2000 BC+
Silk

10th Century
Cat Gut

1930s
Synthetic Polymers

1950s
Staple

2000
Glue

Close / Heal a Surgical Wound
[Example Goal and Market Definition]

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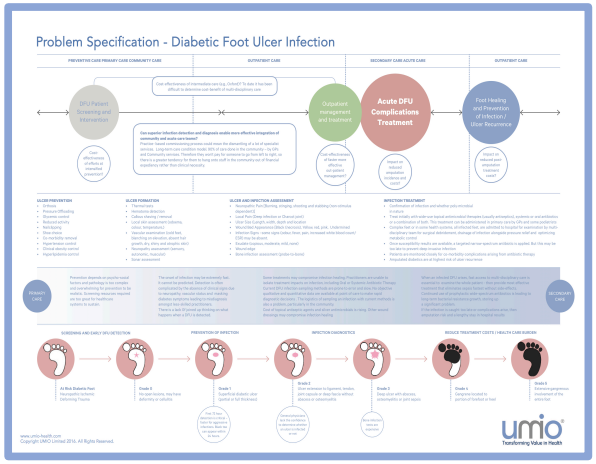
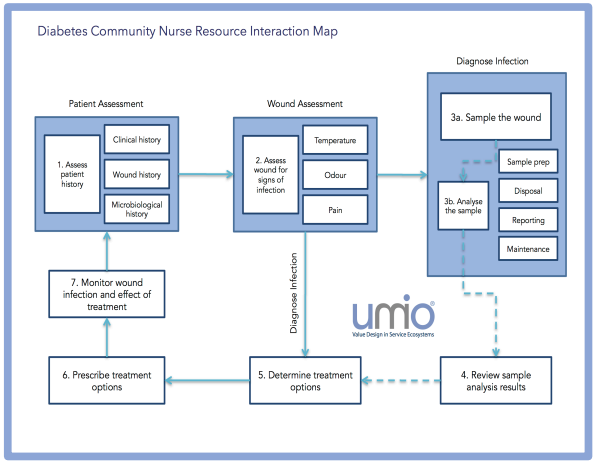
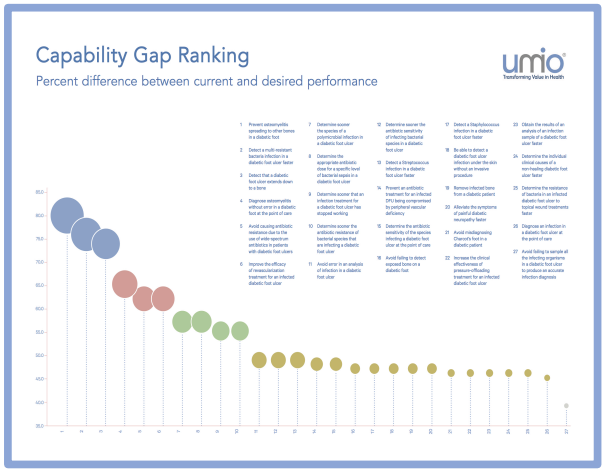
Examples of ecosystem and problem analysis, and co-creative outputs. (NB: More can be shown on request)



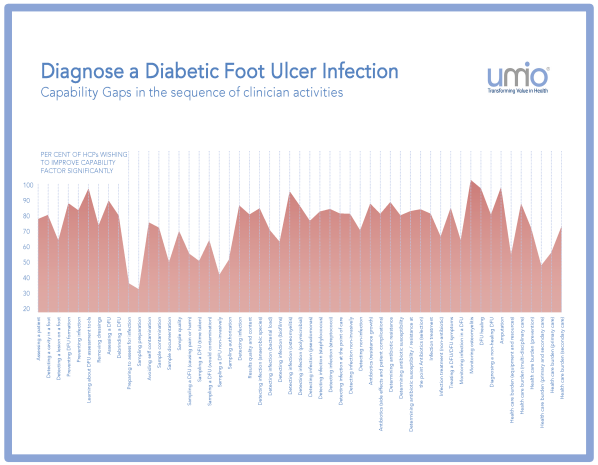
Ecosystem Problem Situation Map



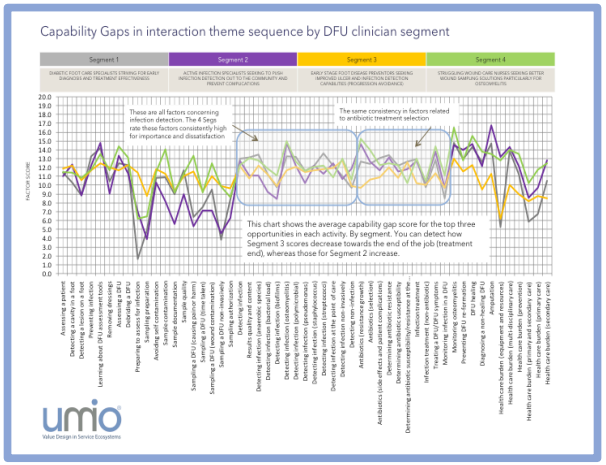
Actor-Resource Interactions Maps



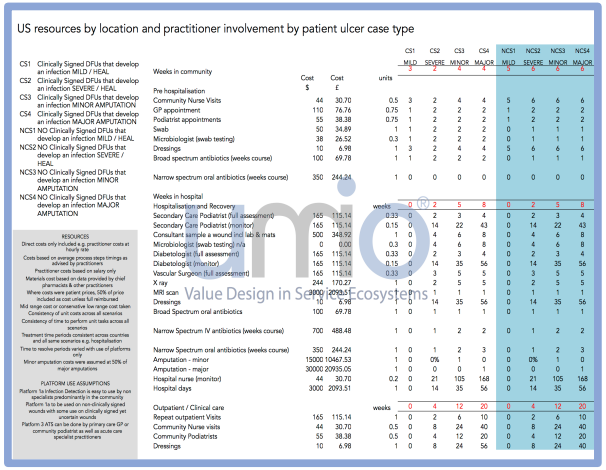
Actor Resource-Capability Gap Ranking



Ecosystem Practices Performance Analysis



Ecosystem Segmentation and Practice Performance Analysis



Intervention Cost and Value Model Single Country with Multi-Scenarios

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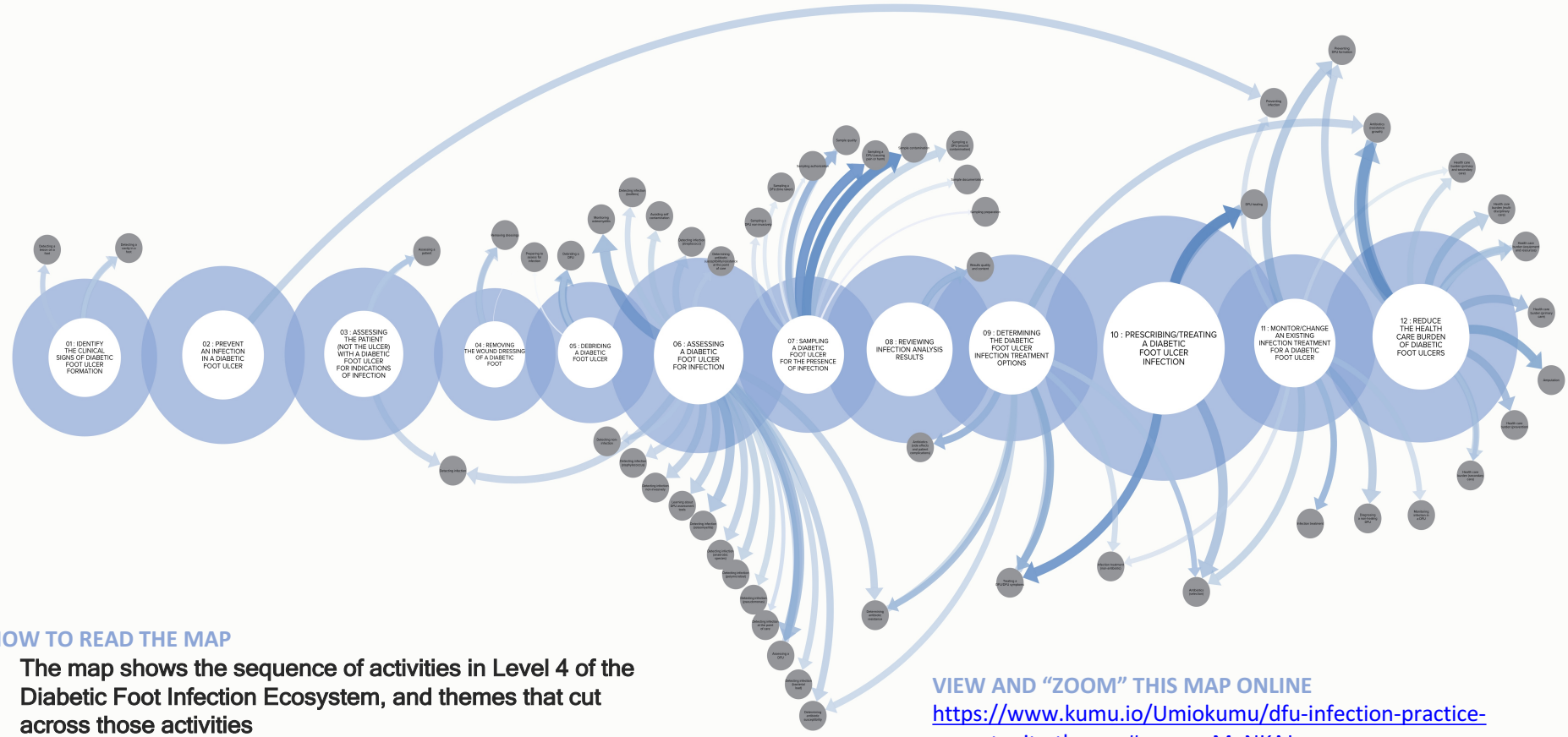
Opportunity map by activities and themes



HOW TO READ THE MAP

- The map shows the sequence of activities in Level 4 of the Diabetic Foot Infection Ecosystem, and themes that cut across those activities
- The bigger the blue circle, the greater the problem / degree of unmet need in the activity step
- The bluer or wider the connection, the greater the problem / opportunity in the theme

VIEW AND "ZOOM" THIS MAP ONLINE

https://www.kumu.io/Umiokumu/dfu-infection-practice-opportunity-themes#map-ocMaNKAJ

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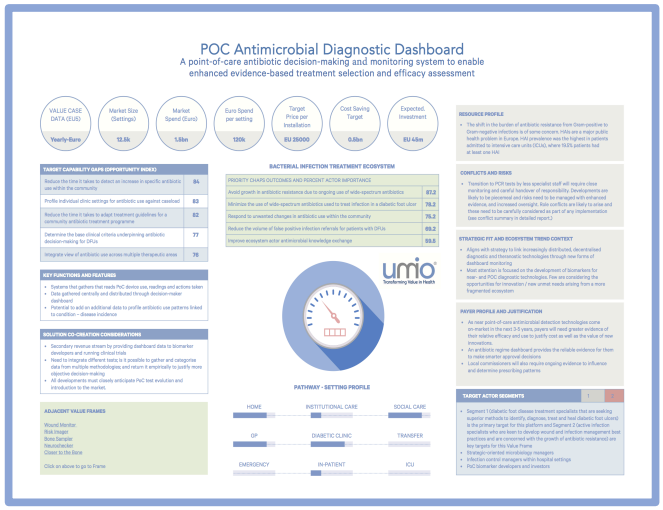
Co-Creating Value Frames and Concepts

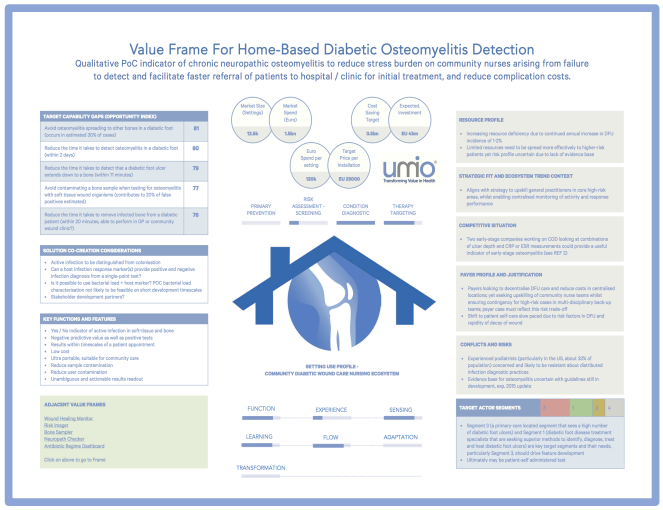
An Umio Value Frame is a thematic statement of possibility used to design multiple value propositions and ecosystem strategy and ultimately, to co-create or refine solutions.

Each Frame contains problem evidence, actor unmet needs, ecosystem resource gaps, constraints to overcome, emergent contexts, priority outcomes and problem paradoxes as well as measures of potential value, whether commercial and/or health system. An early business model design may be included in each Frame too.

Value Frames allow for further dialogue, collaboration and engagement around opportunities with both internal and external stakeholders.

Eight Value Frames were co-created in total for the DFU ecosystem study, each linked to the ecosystem segmentation. These are shown as P0-P7 on the next slide. Each is populated with a full URS/FRS and segment adoption model.





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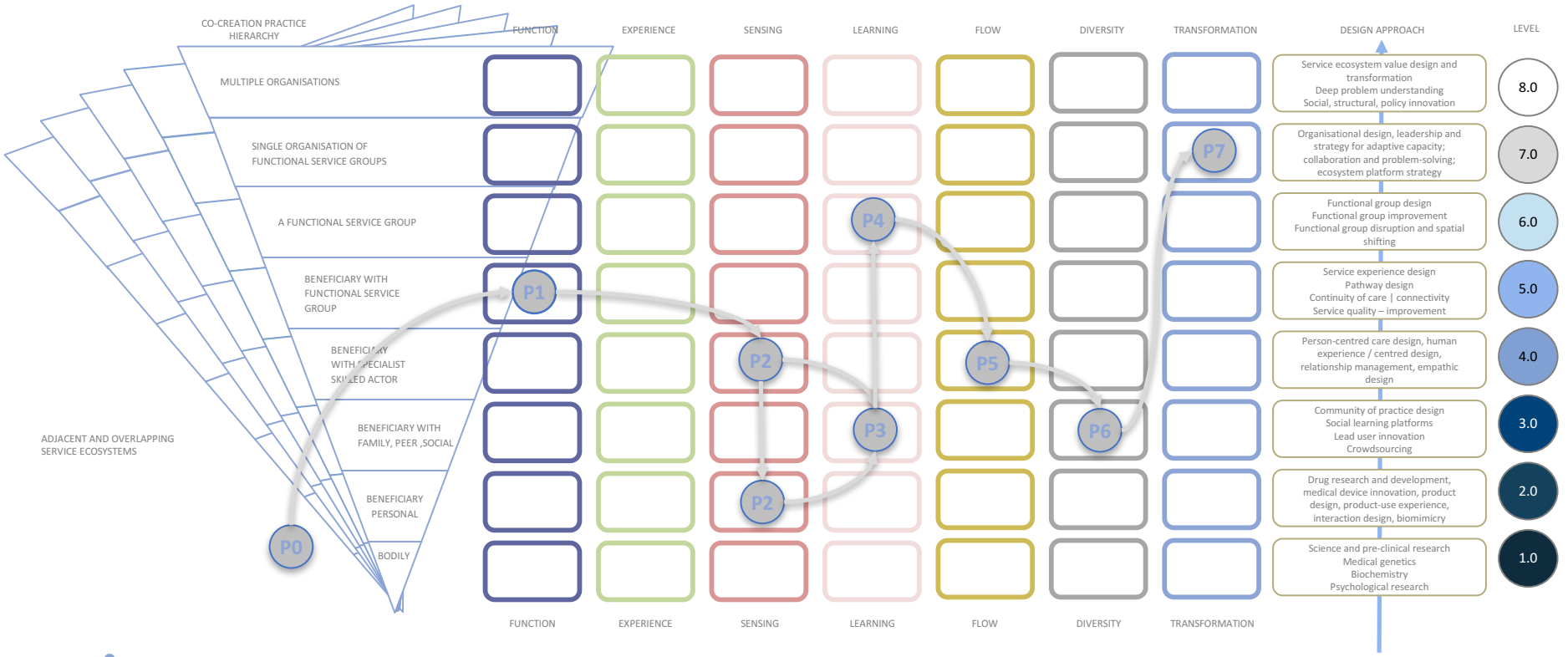
The eight defined Value Frames and Strategic Value Design Map (high-level summary only)

- **P0** POC DFU Detection and Infection Prevention
- **P1** Near Patient Testing for MRSA
- **P2** POC Qualitative Active Infection Detection (Yes / No)
- **P3** POC Wound Healing Status Indication
- **P4** POC Active Infection Detection with Speciation
- **P5** POC Active Infection Detection with Speciation, Infection Management and Monitoring, Wound Management and Healing
- **P6** POC Antibiotic Treatment Selection and Appropriability
- **P7** POC Antimicrobial Diagnostic Dashboard



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Study impact

- Umio opportunity data, segmentation, concept specifications, economic models, ecosystem plans and all insights were licensed by Scottish Enterprise (formerly ITI Scotland) to Mölynycke

- Mölnycke used the insights (supported by technology capabilities at Edinburgh University) to make its first step into the wound diagnostics market, investing in a new research and development team in Scotland in 2013, working with a consortium, PHYESTA

- They began work on developing a near-patient MRSA test for hospital admissions (concept P1). After two years, Detection was achieved in less than 1 hour straight from mock wound fluid without any extensive sample preparation steps. The sensitivity of detection was already near or above the level required for reliable diagnosis of infection.

- Formation of MHC Scotland also represents the first (and so far only) international inward investment to the Edinburgh BioQuarter which is an important part of Scottish Enterprise's delivery plan for economic benefit from the life sciences.

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